

From The Annals of Thoracic Surgery June 2003; 1815-19

“Replacement of the aortic valve in patients under 50 Years of Age: Long-Term Follow-Up of the St. Jude Medical Prosthesis”

Emery, et al. – Retrospective study – 271 aortic valve patients 18-50 years of age implanted between October 1977 and 1997 (1957 patient years)

• Proven Durability over 20 Plus Years

“1.5% of patients underwent valve replacement, a much lower incidence than that for replacement of bioprosthetic valves as demonstrated by Khan et al who reported a valve bioprosthetic failure rate of more than 50% at 20 years.”¹

“Structural failure did not occur. Freedom from mechanical failure for the SJM aortic prosthesis in young patients for longer than 20 years was 100%.”¹

“After seven years, the annual risk of undergoing reoperation increases progressively with time for tissue valves.”²

• Low Complication Rates (See Figures 2-4)

Figure 4. Patient Demographics^{5,6}

Study Cohort	Implant Period	No. Patients	Age at Implant	Valve Position
ATS	1994-1999	685	9-80	AVR
CMI	1987-1992	1036	2-83	AVR, MVR, or AVR + MVR
SJM	1977-1997	271	18-50	AVR

The comparison charts show data from several different studies and are intended to provide a general, rather than specific, comparison. Methodology, definitions, and other variables may differ between the studies.

• Quality of Life with Anticoagulation

“Anticoagulation does not interfere with quality of life and younger patients can lead active lifestyles despite lifelong anticoagulation.”¹

• INR levels maintained at 1.8-2.5¹

“Implanting a tissue valve does not guarantee the elimination of anticoagulation therapy.”²

Figure 1. Actuarial Freedom from Reoperation for Aortic Tissue and Mechanical Valves, Khan et al.²

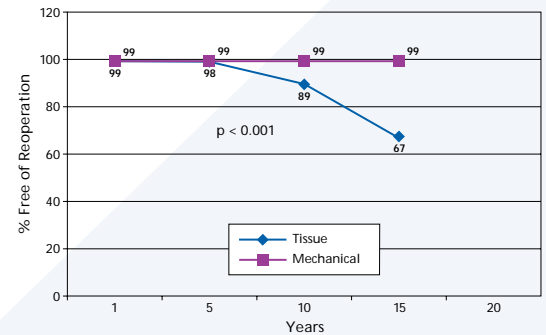


Figure 2. Thromboembolism Rates (per patient year)

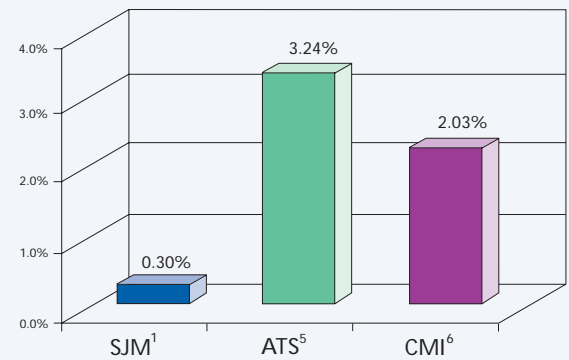
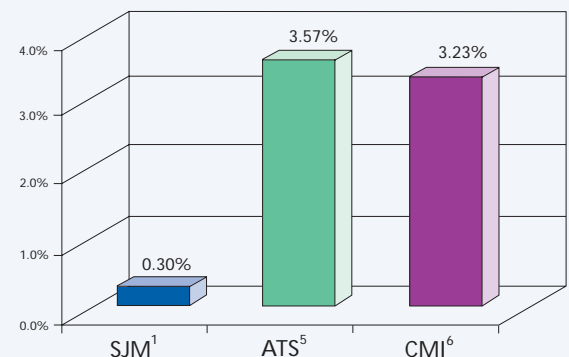


Figure 3. Hemorrhage (major, per patient year)



¹Emery R. et al. Replacement of the Aortic Valve in Patients Under 50 Years of Age: Long-Term Follow-Up of the St. Jude Medical Prosthesis. Ann Thorac Surg 2003;75:1815-9.

²Khan S. et al. Twenty year comparison of tissue and mechanical valve replacement. J Thorac Cardiovasc Surg 2001;122:257-69.

³Hata M. et al. Mid-term Results of the ATS Open Pivot Bileaflet Mechanical Prosthetic Heart Valve. Ann Thorac Cardiovasc Surg 2000;6:34-38.

⁴Aagaard J. et al. Twelve Years' Clinical Experience with the CarboMedics Prosthetic Heart Valve. J of Heart Valve Disease 2001;10:177-189.

⁵FDA Data, Summary of Safety and Effectiveness, www.fda.gov/cdrh/pdf/0990046.html.

⁶FDA Data, Summary of Safety and Effectiveness, P900060.

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St. Jude Medical prosthetic heart valves are indicated for use as replacement valves in patients with a diseased, damaged, or malfunctioning native or prosthetic valve. Possible side effects for all valvular implants include, but are not limited to: regurgitation, thromboembolic phenomena, resistance to flow, infection, hemolysis, dysrhythmias, and prosthetic dehiscence or failure. Anticoagulation is recommended for patients with mechanical valve implants. Please see the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings and instructions for use.

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